

## **II. REMARKS**

### **A. Status of the Claims**

Claims 6-8, 13-16, 24 and 27-41 are pending.

### **B. Double Patenting**

Claims 6-8, 13, 24 and 27-38 were rejected under judicially created doctrine of obviousness-type double patenting over claims 1-19 of the grandparent case (U.S. Patent No. 5,958,459).

Claims 6-8, 13, 24 and 27-38 were rejected under judicially created doctrine of obviousness-type double patenting over claims 1-13 of the parent case (U.S. Patent No. 6,143,322).

Applicants acknowledge the double patenting rejections and submit that filing of the terminal disclaimers will be considered upon indication that claims are otherwise allowable.

### **C. Claim rejection under 35 U.S.C. §103**

Claims 6-8, 13-16, 24 and 27-41 remain rejected under 35 U.S.C. §103(a) over Goldie et al. (U.S. 4,844,909) in view of Oshlack et al. (U.S. Patent No. 5,286,493).

The rejection is respectfully traversed for the reasons set forth in the response filed on July 13, 2009, herein incorporated by reference.

Applicants respectfully submit that the combination of the cited references does not teach or suggest the specific release profiles recited in independent claims 6, 24, 35 and 37

(combinations of (i) the specific mean  $C_{\max}$ , (ii) specific mean  $T_{\max}$  and (iii) a duration of therapeutic effect for 24 hours).

In response to the Examiner's statement on page 11 of the Office Action that "[i]t is Applicant's burden to show factual evidence showing any differences in release in a side-by-side comparison," the Examiner's attention is respectfully directed to Tables 5, 6 and 7 of the Goldie reference which show that that mean maximum plasma concentrations provided by Formulation 1 of the Goldie reference is not the same as the presently claimed mean maximum plasma concentrations.

In response to the Examiner's statement on page 10 of the Office Action that "the teachings of Oshlack still read on the limitation of relative humidity from about 60 to 100%, since ambient humidity is within the lower end of the claimed range," Applicants respectfully note that "the relative humidity under 'dry conditions' in the oven" in Example 3 of the Oshlack patent "was 9% at 60°C." *Column 11, lines 15-29*. Applicants further note that, in the Oshlack patent, the coatings of Examples 7-13 were cured "at 45° C **dry**." *See column 13, lines 32-36; column 14, line 29, and column 17, line 32 (emphasis added)*. Accordingly, Applicants respectfully submit that the Oshlack reference does not read on the curing step recited in claims 6, 24 and 37 (curing "for about 24 hours or more at a temperature greater than the glass transition temperature of the hydrophobic polymer and at a relative humidity from about 60% to about 100%" as recited in claims 6, 24 and 37).

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

### **III. CONCLUSION**

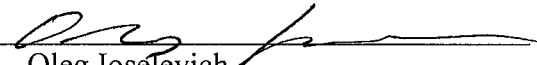
An early and favorable action on the merits is earnestly solicited. The Examiner is specifically authorized to contact the undersigned by telephone in the event a telephone

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interview would advance the prosecution of the application.

Respectfully submitted,  
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